

What is claimed is:

1. A method of making 2-butyl-3-[2'-(triphenylmethyltetrazol-5-yl)-biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one comprising the step of reacting 2-butyl-1,3-diaza-spiro[4.4]non-1-ene-4-one and 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1*H*-tetrazole in the presence of a phase transfer catalyst in a reaction system comprising first and second phases.
2. The method of claim 1 wherein the first phase comprises an aromatic or aliphatic hydrocarbon and the second phase comprises water.
3. The method of claim 2 wherein, prior to reaction, the 2-butyl-1,3-diazaspiro[4.4]non-1-ene-4-one is in solution in aqueous base.
- 15 4. The method of claim 3 wherein the aqueous base is selected from the group consisting of KOH, NaOH and LiOH.
5. The method of claim 4 wherein the aqueous base is aqueous KOH.
- 20 6. The method of claim 2 wherein, prior to reaction, the 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1*H*-tetrazole is in solution in an aromatic or aliphatic hydrocarbon.
7. The method of claim 6 wherein the 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1*H*-tetrazole is in solution in an aromatic hydrocarbon that is toluene.
- 25 8. The method of claim 2 wherein the 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1*H*-tetrazole is in solution in an aliphatic hydrocarbon.

9. The method of claim 1 wherein the phase transfer catalyst is a quaternary ammonium compound.

10. The method of claim 9 wherein the quaternary ammonium compound is tetrabutyl 5 ammonium hydrogensulfate.

11. A method for making irbesartan comprising the steps of: preparing 2-butyl-3-[2'-(triphenylmethyltetrazol-5-yl)-biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one prepared according to the method of claim 1; heating the combination to a temperature of 10 about 20° C and about 95° C; separating the first and second phases; removing solvent from the first phase to obtain a residue; providing a mineral or sulfuric acid acidified solution of the residue in a water-miscible solvent, basifying the solution in water-miscible solvent with an inorganic base; removing water-miscible solvent from the solution; separating trityl alcohol so formed; and recovering irbesartan.

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12. The method of claim 11 wherein the water miscible solvent is acetone.

13. The method of claim 11 wherein the basification is with an inorganic base to a pH of about 8 to about 12.

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14. The method of claim 13 wherein basification with inorganic base is to a pH of about 9 to about 10.5.

15. In a method of making irbesartan, the step of combining, in the presence of a phase 25 transfer catalyst, a solution of 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole in a first solvent that is an aromatic or aliphatic hydrocarbon and a solution of 2-butyl-1,3-diazaspiro[4.4]non-1-ene-4-one in a second solvent comprising water and an inorganic base, whereby first (organic) and second (aqueous) phases are formed.

16. The method of claim 15 wherein the aromatic or aliphatic hydrocarbon is the aromatic hydrocarbon toluene.

17. The method of claim 15 wherein the phase transfer catalyst is tetrabutylammonium  
5 hydrogensulfate.

18. The method of claim 15 wherein the inorganic base is KOH.